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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/670,781
Filing Date: September 27, 2000
Appellant(s): DALY, PAUL C.

Timothy Nathan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/20/09 appealing from the Office action mailed 3/13/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence relied upon in the rejection of claims under appeal. Copies of the original publications or on-line full text versions, corresponding to the original Dialog abstracts, have been previously included, scanned, and mailed with the original Answer mailed 3/1/07. The copies of the original documents/full text documents were only placed in the record to confirm the original date of the text relied upon in the Final Rejection and Answer.

4,054,207 LAZURE ET AL 10-1977

Blass et al, Sucrose as an Analgesic for Newborn Infants, Pediatrics, Vol. 87,
No.2, 2, 1991, pp.215-218

Stevens et al, The Efficacy of Developmentally Sensitive Interventions and
Sucrose for Relieving Procedural Pain in Very Low Birth Weight Neonates,
Nursing Research, Jan/Feb 1999, Vol. 48, No. 1, pp.35-43

Stevens et al, The Efficacy of Sucrose for Relieving Procedural Pain in
Neonates-A Systematic Review and Meta-Analysis, Acta Paediatr 86:
837-42, 1997

Franck, The Use of Sucrose Analgesia to Relieve Procedural Pain In Neonates,
Children's Medical Ventures, Vol. 1, Issue 1, 3 pgs, 2000

3,654,746 BECKERS 4-1972

4,597,242 HENDRIKS ET AL 7-1986

4,211,338 BUBLITZ 7-1980

Seattle Post Intelligencer 11/14/1990, p. C11

Wisconsin State J. 2/6/1991, p.4A
San Francisco Examiner 11/1/1992, p. T2
New Food Products in Japan 10/1991
Food Engineering 1979, 51 (8) pp. 43-44
2,138,241 KOCH ET AL 11-1938
4,165,594 CORBIC 8-1979
4,875,620 LANE 10-1989
5,429,262 SHARKEY 7-1995
3,390,766 STOCKDALE 7-1968
3,478,489 MEISNER 11-1969
3,414,414 CHRISTINE ET AL 12-1968
Appellant's Admission of the Prior Art

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 6, 7, 10, 21 and 23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazure et al('207) in view of applicant's admission of the prior art as evidenced by Blass et al (2/91), Stevens et al (January/February. 1999), Stevens et al (1997) and Frank (2000), further in view of Beckers ('746), Hendricks et al ('242), Bublitz (4,211,338), further in view of Seattle Post-Intelligencer (11/14/90) and Wisconsin State J. (2/6/91, p. 4A), further in view of San Francisco Examiner (11/1/92),

New Food Products in Japan (10/91) and Food Engineering (51, 8, 43-4, 1979), further in view of Koch et al ('241), Corbic ('594), Lane ('620), Sharkey ('262), Stockdale ('766), Meisner ('489) and Christine et al ('414).

In regard to claim 1, Lazure et al discloses a packaged product comprising a cup-shaped container defining a cavity therein, opening to a mouth, a volume of product within the cavity, and a cover disposed over the mouth and sealing the product in the cavity. Claim 1 differs from Lazure et al in that claim 1 specifically recites that the product in the cup shaped container is a solution comprising sucrose and water. As disclosed, the intended use of this solution is to be administered to a newborn to ease pain during a procedure. However, the article claims just recite the solution in a conventional cup shaped container. Lazure et al discloses that his cup shaped containers can contain unit doses of medicines or individual servings of foods (col. 1, para. 1). It is not entirely clear how to categorize appellant's product, since the sugar solution is edible, but also plays a medicinal role. In any case, Lazure et al is considered to be a general teaching, fairly teaching that it was notoriously old in the packaging art to package both medicinals and food in cup shaped containers to provide unit portions/single servings. As evidenced by appellant's admission of the prior art, found on pages 2 and 3 of the specification, and further evidenced by Blass et al, Stevens et al (1999), Stevens et al (1997) and Franck, the recited sucrose/water solution, and in the recited concentration, was not only conventional in the art, but was also used for appellant's intended function of reducing pain in newborns. In fact, the secondary art only differs from claim 1 in the conventional container structure. Note that claim 1 has

no indication of the volume of the solution present in the cup shaped container. Since appellant is clearly not the inventor of the sucrose solution, as evidenced by the art taken as a whole, to modify Lazure et al and package the specific medicinal/food, conventional sucrose solution in the conventional cup shaped container would have been obvious – i.e., an obvious substitution of one conventional product for another conventional product to be packaged. Note that although claim 1 does not recite a unit dose portion and container size, it would have been obvious to provide unit portions or doses and accompanying appropriately sized containers, rather than bulk portions and bulk containers in view of the art taken as a whole. Beckers can be relied on as further evidence of the conventionality of employing cup shaped containers for providing individual portions of foods and non foods and Hendriks et al and Bublitz are relied on as further evidence of the equivalency of cup shaped containers for both foods and pharmaceutical products. Claim 1 also recites that the sugar solution and the interior of the container are in an aseptic state. Of course, aseptic packaging is notoriously conventional. In any case, Hendricks et al disclose the conventionality of providing pharmaceuticals and foods in cup shaped containers in an aseptic state. Since Lazure et al also discloses foods and medicinals in cup shaped containers, to provide the contents of the containers of Lazure et al in an aseptic state for its art recognized and appellant's intended function of a sterile environment would have been obvious. Finally, claim 1 recites that the cup shaped container has a greater width than depth. Beckers can be relied on to teach that the recited dimensional relationship is well established in the art, and particularly with cup shaped containers, and to modify Lazure et al and

make a conventional dimensional change is seen to have been an obvious matter of design. Seattle Post Intelligencer and Wisconsin State J. are relied on as further evidence of the conventionality of providing sugar solutions. San Francisco Examiner, New Food Products in Japan and Food Engineering are relied on as further evidence of single serve/dose medicinal packaging and single serve liquid sugar packaging. Koch et al, Corbic, Lane, Sharkey, Stockdale, Meisner and Christine et al are relied on as further evidence of the conventionality of employing single serve or single use cups for all types of products – edible, medicinal or inedible – in all sizes and shapes of cups. See in this regard, In re Gorman 18USPQ2d 1888, wherein the Court noted that where teachings relied upon to show obviousness were repeated in a number of references, the conclusion of obviousness was strengthened. In regard to claim 2, Lazure et al discloses that the cover includes a lateral portion that protrudes beyond the rest of the cover and the flange. In regard to claims 3,4,6, and 7, Lazure et al discloses the conventionality of the cover being sealed to the peripheral flange; the provision of a peripheral flange; the peripheral flange having a protrusion, etc. Claim 10 recites a specific concentration of sucrose and water, which concentration is intended to be used to alleviate pain when administered to newborns. As noted above, Blass et al, the two Stevens et al references and Franck teach sucrose solutions for appellant's intended use and also disclose that appellant's specifically claimed solution is conventional. To package the specific conventional solution in the conventional container of Lazure et al would therefore have been obvious, in view of the art taken as a whole and the reasons given above. Claim 23 combines a number of recitations already addressed and is

rejected for the reasons given above (similarly for claim 29). Note that claim 29 also recites that the width of the mouth of the container is sized to receive at least a portion of an object, but since no object is recited, this reads on any object. Claims 30 and 31 recite that the width of the container is sized to receive a pacifier and syringe, respectively. The art taken as a whole discloses it was known to provide a sucrose solution containing receptacle wherein a pacifier or syringe is to be dipped into the solution. To modify the combination and provide the cup shaped container with a mouth sufficient to receive a pacifier or syringe for its art recognized and appellant's intended function would therefore have been obvious. Of course, containers that are to be associated with syringes or droppers are notoriously conventional.

Claims 12, 13, 15, 16, 22, 17, 19, 20 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's admission of the prior art as evidenced by Blass et al (2/91), Stevens et al (January/February 1999), Stevens et al (1997), Frank (2000), Seattle Post –Intelligencer (11/4/90) and Wisconsin State J (2/6/91 p. 4A), in view of Lazure et al, Beckers, Hendriks et al and Bublit, further in view of Koch et al, Corbic, Lane, Sharkey, Stockdale, Meisner, Christine et al, further in view of San Francisco Examiner, New Food Products in Japan, and Food Engineering.

This rejection employs all of the same references that are relied upon in the rejection of the article claims 1-4,6,7,10,21 and 23-36 above, but placed in a different order, in view of the fact that claims 12,13,15,16,22,17,19,20, and 37-39 are method claims.

In regard to claim 12, appellant's admission of the prior art, as further evidenced by Blass et al, the two Stevens et al references, and Franck, teach preparing a solution comprising sucrose and water and administering a selected volume dose of the solution orally to a neonatal infant. Claim 12 differs from appellants admission of the prior art, as further evidenced by Blass et al, the Stevens et al references and Franck, in that the solution is packaged in single use/dose containers and shipped to its intended site of use. As discussed above, and as disclosed by Lazure et al and the art taken as a whole, it is notoriously conventional in the packaging art to package unit doses of all types of conventional products including medicines and foods in individual, single use disposable containers and assembling a plurality of containers for shipping and use. To modify appellant's admission of the art as further evidenced by Blass et al, the Stevens et al references and Franck, and provide the sucrose/water solution pain reliever in such conventional packaging for its art recognized and appellant's intended function would therefore have been obvious. Note that although the claims do not positively recite it, Seattle Post Intelligencer and Wisconsin State J. teach dipping syringes or pacifiers in sucrose solutions and administering the solutions to infants to relieve pain. The remainder of the method claims contain limitations addressed above in the rejection of the article claims and are rejected similarly.

(10) Response to Argument

All of appellant's arguments have been fully and carefully considered but are not found to be convincing.

It is first noted that many of the urgings that have been made are directed to limitations not found in the claims. Urgings are made that are directed to single use containers, with the implication of a small amount of product. It is noted, however, that many of the claims do not positively recite a volume of total product vis-a-vis the container. In fact, only claims 12 and 17, and the claims dependent thereon, recite "single-use containers" and a "volume selected for a single patient", respectively. Since the claims have been, and would be rejectable, even if the claims all positively recited the amount of sucrose solution, the urgings relative to single use containers and amounts have been treated above and below.

It has been urged that the pending claims are patentable under 35USC103 because the supplemental references were not from within the inventor's field of endeavor or reasonably pertinent to the problem sought to be solved is totally unconvincing. This urging is a "non-analogous" art type of urging. Contrary to what has been urged, the art applied is all analogous, and the problem is also analogous as well. Urgings are made attempting to narrow the field of endeavor to the minutely narrow childrens medical device art and then these urgings would choose to have the reader wear blinders so that one could not see the rest of the world beyond the childrens medical device art. The fact is, the art taken as a whole teaches that the recited sucrose solution in bulk quantity is well established in the art, but for reasons of convenience, cleanliness, avoiding wastefulness, etc, appellant chooses to provide small, single use quantities of the sucrose solution in containers. Appellant has urged that one of ordinary skill would not likely reference the container art to find the answer to the problem. If the

problem is that the sucrose solution, in bulk containers, is inconvenient, unsanitary and wasteful, where else would one look to but in the container art where all types of products are contained in all types of sizes including bulk and single use/dose? It is urged that the rejection is based on improper hindsight. Clearly it is not. The motivation comes from the art taken as a whole. The art taken as a whole teaches that it was notoriously conventional to provide medicines and foods in single serve or single dose cup shaped containers; that it was notoriously conventional to provide medicinals and foods in aseptic packages; that it was well established to provide a sterile sucrose solution in the recited concentration as an analgesic for newborns; and it was conventional to administer the sterile sucrose solution in very small amounts. These teachings, or evidence, are all within the art, taken as a whole. Since the art taken as a whole teaches it was well established to provide medicinals in unit dose, single use or serve cup shaped containers, and since the recited sterile sucrose solution is conventional and known for its use as an analgesic, to package the conventional sterile sucrose solution in the conventionally recited concentration in a conventional single use/serve cup shaped package would have been unequivocally obvious. In fact, the references scream out to be combined. The urging that it is improper to go outside the childrens medical device art implies that only a single reference teaching the conventional sucrose solution in the conventional container would be acceptable as a rejection. The rejection is not based on a single reference under 35USC102, anticipation, but rather on a combination of references under 35USC103, obviousness. Note, too, that if the problem is inconvenience, and the potential for waste and

contamination, these issues are those that are universally recognized as being addressed by single use/serve containers. That is, whether the products are foods, such as mustard and ketchup, or single dose medicines, the use of single use/serve containers provide greater convenience, less waste and less chance of contamination, than large, bulk-type containers.

It has also been urged that there is no reference to suggest the modification. This urging has been addressed above. In has further been urged that the time between the references is of significance in determining patentability. In response, it is noted that patentability is predicated on what the art teaches, not at any one date of one of the references, but what the art, taken as a whole, teaches at the time of applicant's invention (i.e., the effective filing date of the application). It has been urged that the source of appellant's stated problem was time, inconsistency in hand mixing, potential for contamination, etc. Appellant did not invent these sources of the problem, nor was he the first to recognize them. The problem, if you will, existed before appellant's invention. However, these sources of the problem is why so many products, both medicinal as well as food, are pre-made and pre-packaged. That is, a pre-prepared product saves the time it would have taken to make it, and pre-packaged products are sanitary and convenient. Note, too, the secondary art can teach both the problem and its solution. Inherent in any single dose/serve container of food or medicinal is the inherent solving of problems of inconvenience, time and cleanliness.

It has been also urged that the examiner failed to properly consider the secondary considerations raised in the Declarations filed 8/31/04. The secondary

considerations were carefully considered, but were not found to present any unexpected evidence, but instead presented evidence that would have been expected by one of ordinary skill in the art.

The Declaration filed on 8/31/04 by Ms. Bush under 37CFR 1.132, urging commercial success, has been fully and carefully considered but was found to be insufficient to overcome the prima facie case of obviousness. The Declaration compares the sales of packages of sucrose solution to packages of a product that warms the sole of the infants foot. It is not clear how effective the latter is in providing pain relief to a newborn. The use of a sucrose solution as an analgesic for newborns is well established in the art. Therefore one would expect sales to be better for the well recognized sucrose analgesic solution. The Declaration also attributes the sales to the convenience of the aseptically packaged container filled with the sucrose solution. However, the convenience of single use containers containing single doses of medicinals or single serve foods is not an unexpected result. It is an expected result. Single use containers for all types of products, even non-edible, non-medicinal products are provided for the convenience and the ability to discard the package once it has been opened, and as much of its contents, as desired, is used. It is also noted that single dose/use aseptic baby bottles, containing pre-prepared formula, have been employed in hospitals for newborns for many years because of their convenience and sanitary state.

The three Declarations filed on 8/31/04, by Doctors Yohanan, Guttenberg and Granger, respectively, under 37CFR1.132, urging long felt need, were also carefully considered but were not found to overcome the rejection. All three declarations employ

the same exact language and urge a long felt need, attesting to the convenience and safety of the product. However, this is the same advantage that any aseptic medicinal or food single dose/serve product would possess. This is why one manufactures and why one uses conventional single serve/dose containers. As noted several times above, these are expected results and not unexpected results. Note, too, as also noted above, many of the claims are not even directed to a single dose/serve product.

Therefore, the commercial success and long felt need showings are not convincing; they rely on expected (not unexpected) results; and when measured versus the art taken as a whole do not outweigh the strong case of prima facie obviousness.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Steve Weinstein/
Primary Examiner, Art Unit 1794

Conferees:

/Milton I. Cano/
Supervisory Patent Examiner, Art Unit 1700

/Gregory L Mills/
Supervisory Patent Examiner, Art Unit 1700

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